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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/911,569 | 07/23/2001 | Pamela Hawley-Nelson | 32-95D | 8436 |

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| EXAMINER | |
|---|---|
| SULLIVAN, DANIEL M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | |

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/911,569 | HAWLEY-NELSON ET AL. | |
| | Examiner | Art Unit | |
| | Daniel M Sullivan | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-41 and 48-63, drawn to a composition comprising one or more nucleic acid molecules, one or more peptides or proteins and one or more transfection agents, classified in, for example, class 536, subclass 23.1.

II. Claims 42-47 and 64-71, drawn to a composition comprising a component of transfection agent covalently linked to a peptide or protein or comprising a peptide or protein or a modified peptide or protein capable of enhancing transfection, classified in class 424, subclass 450.

III. Claims 72-74, drawn to a NLS sequence modified by covalent bonding to a nucleic acid-binding group, classified in class 435, subclass 300.

IV. Claims 75-77, drawn to a peptide comprising a Tat sequence modified by covalent bonding to a nucleic acid-binding group, classified in class 435, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group I is not limited to comprising a transfection agent covalently linked to a peptide or protein or comprising a protein capable of enhancing transfection as is the subcombination of Group II. The subcombination has separate utility such as to deliver a protein, rather than a nucleic acid, into a cell.

Inventions I and II are each related to the peptides of Inventions III and IV as combination and subcombination. The combination as claimed does not require the particulars of the subcombinations as claimed because the combinations are not limited to comprising the specific peptides to which Groups IV and V are directed. The subcombination has separate utility such as to raise an antibody against the NLS or Tat proteins of Groups IV and V.

Inventions III and IV are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and comprise mutually exclusive characteristics (*i.e.*, the NLS to which Group III is limited and the Tat sequence to which Group IV is limited).

Groups I and II are further restricted to a single named peptide or protein and a single named transfection agent. Each named peptide or protein and each named transfection agent is a structurally and functionally distinct chemical entity. Therefore, absent evidence to the contrary, each composition comprising a distinct peptide or protein and transfection agent is presumed to represent a distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*

Compositions directed to specific peptides or proteins and transfection agents are linked in the following way:

Group I

Claim 1 links all transfection agents and all proteins set forth in claims depending therefrom (*i.e.*, the cationic lipids of claim 6 and the dendrimers of claim 8; the animal, bacterial or viral peptides and proteins of claim 20)

Claim 6 links all cationic lipids set forth in claims 10 and 12.

Claim 10 links the monovalent cationic lipids set forth in claim 11.

Claim 12 links the polyvalent cationic lipids set forth in claim 13.

Claim 8 links the dendrimers set forth in claim 15.

Claim 20 links all animal proteins or all bacterial proteins or all viral proteins.

Claim 24 links the nuclear localization peptides set forth in claim 31.

Claim 25 links the fusagenic peptides or proteins set forth in claim 31.

Claim 26 links the receptor-ligand peptides or proteins set forth in claim 31.

Claim 27 links the transport peptides or proteins set forth in claim 31.

Claim 28 links all proteins from each of the viruses set forth in claim 29.

Claim 29 links the viral proteins set forth in claim 31.

Claim 55 links the peptides and proteins of claim 56, and links the dendrimers of claim 60.

Claim 56 links the sub-cellular localization signal sequence, nuclear localization sequence, fusagenic sequence, transport or trafficking sequence, receptor-ligand sequence or cell adhesion sequence of claims 57-59.

Claim 60 links the dendrimers set forth in 62.

Group II

Claim 42 links the lipid transfection agent of claim 43 and the dendrimer of claim 46.

Claim 43 links the cationic lipid of claim 44 and the neutral lipid of claim 45.

Claim 65 links the cationic lipid transfection agents set forth in claim 66.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

An election to prosecute the Invention of Group I should also include election of a single monovalent cationic lipid from claim 11, a single polyvalent cationic lipid from claim 13 or a single dendrimer from claims 15 and 62 as well as election of a single peptide or protein from claims 31 and 59. If claims 1 and/or 55 are found allowable, restriction among the linked peptides or proteins and transfection agents set forth in the claims will be withdrawn.

If claim 1 is not allowable, examination will be restricted to a composition comprising a cationic lipid (claim 6) or dendrimer (claim 8), whichever encompasses the species elected from claim 11, 13 or 15. If claim 6 is examined and not deemed allowable, further examination of the composition will be restricted to the monovalent cationic lipids of claim 10 or the polyvalent cationic lipids of claim 12, depending upon the elected species from claim 11 or 13. If claim 8 is examined and not deemed allowable, examination of the composition will be restricted to the

dendrimer species elected from claim 15. If claim 10 is examined and not deemed allowable, examination of the composition will be restricted to the species elected from claim 11. If claim 12 is examined and not deemed allowable, examination of the transfection agent of the composition will be restricted to the species elected from claim 13.

If claim 1 is not allowable, examination of the composition will be restricted to the animal, bacterial or viral protein of claim 20, depending upon the species elected from claim 31. If the broad class of animal, bacterial or viral proteins is not deemed allowable, examination will be restricted to the nuclear localization proteins of claim 24, fusagenic proteins of claim 25, receptor-ligand proteins of claim 26, transport proteins of claim 27, or viral proteins of claim 28, depending upon the species elected from claim 31. If claim 24 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31. If claim 25 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31. If claim 26 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31. If claim 27 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31. If claim 28 is examined and not deemed allowable, examination will be restricted to a single species of virus set forth in claim 29, depending upon the protein species elected from claim 31. If the virus of claim 29 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31.

If claim 55 is not deemed allowable, examination will be restricted to the sub-cellular localization signal sequence, nuclear localization sequence, fusagenic sequence, transport or trafficking sequence, receptor-ligand sequence or cell adhesion sequence of claim 56, depending

upon the species elected from claim 59. If the protein class of claim 56 is not deemed allowable, examination will be restricted to the elected species from claim 59.

If claim 55 is not deemed allowable, examination will also be restricted to the dendrimer of claim 60. If claim 60 is not deemed allowable, examination will be restricted to the dendrimer species elected from claim 62.

An election to prosecute the Invention of Group II should also include election of the cationic lipid of claim 44, the neutral lipid of claim 45 or the dendrimer of claim 46; and should include election of a single lipid transfection agent from claim 66. If claims 42 and/or 65 are found allowable, restriction among the linked transfection agents set forth in the claims will be withdrawn.

If claim 42 is not deemed allowable, examination will be restricted to the lipid of claim 43 or dendrimer of claim 46. If claim 43 is examined and not deemed allowable, examination will be restricted to the elected cationic lipid of claim 44 or neutral lipid of claim 45.

If claim 65 is not deemed allowable, examination will be restricted to the cationic lipid elected from claim 66.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID E. ROMEO
PRIMARY EXAMINER